

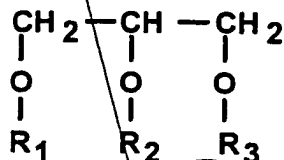
ART 34 AMEND

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Claims

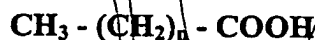
1. Vaccine formulation against a mycobacterium comprising, as adjuvant, one or more substances selected from

- a) monoglyceride preparations having at least 80 % monoglyceride content and having the general formula



wherein R_1 and R_2 is H and R_3 is one acyl group containing from 6 to 24 carbon atoms, and where the acyl chains may contain one or more unsaturated bonds, in admixture with one or more substances selected from

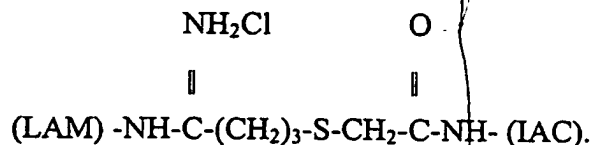
- b) fatty acids of the general formula



where "n" may be varied between 4 and 22, and where the acyl chain may contain one or more unsaturated bonds, and

as immunizing component, an immunogenic product consisting of antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bridge groups, to immunologically active carriers (IAC).

2. Vaccine formulation according to claim 1, wherein the immunologically active carriers (IAC) contain amino groups and said divalent bridge group has the following structural formula



3. Vaccine formulation according to claim 1 or 2, wherein the adjuvant has a monoglyceride preparation content of at least 90 %, preferably at least 95 %, and the acyl chains of the monoglyceride preparation contains 8 to 20 carbon atoms, preferably 14 to 20 carbon atoms, and the acyl chains optionally contains one or more unsaturated bonds, and the immunologically active carriers (IAC) are derived from

polypeptides and are selected from tetanus toxoid, diphtheria toxoid, cholera subunit B or Protein D from *H. influenzae*.

Sub
A
cont
4. Vaccine formulation according to any one of claims 1 - 3, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solution, preservatives and osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters, and anti-oxidative agents.

5. Vaccine formulation according to claim 3 or 4, wherein the adjuvant is a mixture of mono-olein and oleic acid, and possibly soybean oil, and the immunizing component is lipoarabinomannan-tetanus toxoid (LAM-TT).

6. Vaccine formulation according to any one of claims 1-5, wherein the formulation is formulated into a preparation for mucosal administration.

7. Vaccine formulation according to claim 6, wherein the mucosal administration is selected from nasal, pulmonary, oral, rectal and vaginal administration.

8. Aerosol or spray package comprising a tuberculosis vaccine composition according to any one of the claims 1 - 7.

9. Nose-drop package comprising a tuberculosis vaccine composition according to any one of the claims 1 - 6.

10. A method of vaccinating a mammal against a mycobacterium having antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis*, which comprises mucosal administration to the mammal of an protection-inducing amount of a tuberculosis vaccine composition according to any one of claims 1 - 7.